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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,548	01/15/2004	Murali Dharan	114-001	5989

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/758,548	Applicant(s) DHURAN ET AL.	
	Examiner B. Dell Chism	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-10 in the reply filed on 23 January 2006 is acknowledged. Claims 11-14 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Objections

2. Claim 4 is objected to because of the following informalities: claim 4, line two, comprises the term "expose" wherein the tem should be the adjective --exposed--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-6 are rejected under 35 U.S.C. 102(b) as being anticipate by Winkler et al. (2000, Journal of Antimicrobial Chemotherapy, Vol. 26, pages 423-428). Winkler et al. teach vancomycin in water (page 424, right column).

It should be noted that the intended use aspects of the claims were not considered as a limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al. (2000, Journal of Antimicrobial Chemotherapy, Vol. 26, pages 423-428) in combination with Vogt et al. (US 2004/0052841 A1).

Winkler et al. teach the use of powdered vancomycin in water solution in bone graft studies. Winkler et al. teach vancomycin in water at a 1 g/10mL ration, however, Winkler et al. does not teach 1:1 vancomycin to water (weight to cubic centimeter volume. Winkler et al. teach the use for effects on bone repair and eradication of infection.

Vogt et al. teach pharmaceutical compositions comprising vancomycin such as bone cements to treat bacterial infections in localized areas in vivo. Vogt et al do not teach vancomycin in water or saline or Lactated Ringers.

The instant claims are to a composition comprising vancomycin with a biocompatible carrier, i.e. water, saline and Lactated Ringers. The prior art teaches compositions comprising vancomycin with biocompatible carrier (Winkler et al. and Vogt et al.). The prior art teaches the use of such compositions for treatment of infections of the bone tissues of the body or for prevention of such infections due to insult to bony tissues (Winkler et al. and Vogt et al.). The prior art teaches the success of such techniques. Although, the prior art does not teach a paste as instantly claimed, the prior art teaches the application of the compositions to hard and soft tissues of the human and veterinary bodies as resorbable and non-resorbable implants.

The prior art teaches use of vancomycin compositions for treatment of bony tissues for the purposes of fighting infections while bony tissues repair or metallic and non-metallic

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implants are utilized. Even though the instant claims 2 and 7-10 are to a composition with a 1:1 vancomycin to carrier ration, from the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary, i.e. that a 1:1 ration had some unexpected result not obvious to one of skill in the art.

It should be noted that the intended use aspects of the claims were not considered as a limiting factor in the rejected claims for it is the product of the product claims that is under consideration and not the intended use.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4, 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite for the recitation of the phrase “capable of” wherein it is unclear as to whether the “capable of” characteristic is what the compounds of the claims is specifically used for.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The

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examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDC



**B. DELL CHISM
PATENT EXAMINER**